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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
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Cincinnati, OH 45237-3097
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December 12, 2006

WARNING LETTER
CIN-07-31888-08

VIA FEDERAL EXPRESS

Randy Thurman
President/CEO
VIASYS Healthcare
227 Washington Street
Conshohocken, PA 19428

Dear Mr. Thurman:

During an inspection of your medical device manufacturing facility, Tiara Medical Systems, Inc., located at 14414 Detroit Avenue, Suite 205, Lakewood, OH on October 17 through November 3, 2006, an investigator from the United States Food and Drug Administration (FDA) determined that your firm at this location is the specification developer and the complaint handling unit for the continuous, positive air pressure devices. Under section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from Robert Mitchell, Vice President Quality Assurance/Regulatory Affairs & Continuous Improvement, dated November 14, 2006, concerning our investigator's observations noted on the Form FDA 483 that was issued to Tiara Medical Systems. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1) Failure to establish procedures for, and to implement, a complaint handling system that assures all complaints involving the possible failure of a device are investigated. [21 CFR 820.198(a and c)]

   Specifically, nine of the 77 complaints reviewed by the investigator state no investigation was performed because the devices were not returned. Your "Complaint Handling" procedure states

"no investigation is necessary if the product sample(s) are not available for analysis". Therefore no investigation was made and no trending of these complaints was conducted.

Your response to this observation appears to be adequate.

2) Failure to include the details of a complaint in the records of complaint investigations. [21 CFR 820.198(e)]

Specifically, a total of 12 of the 77 complaints reviewed by the FDA investigator had incomplete descriptions of the customer's reported failure.

Your response to this observation appears to be adequate.

3) Failure to fully document the design input requirements. [21 CFR 820.30(c)]

Specifically, for the SNAPP and SNAPP-X design projects, the design inputs, dated 11/28/05 are incomplete, ambiguous, and do not address all the needs of the user.

4) Failure to establish, and implement a design output procedure that allows for an adequate evaluation of conformance to design output requirements. [21 CFR 820.30(d)]

Specifically, the design outputs for the SNAPP and SNAPP-X design projects do not ensure that the design inputs have been met. For several of the inputs, it is not clear which outputs conform to specific inputs.

5) Failure to implement a design review procedure that assures that design reviews are performed at the appropriate stages of development. [21 CFR 820.30(e)]

Specifically, the "Design Control" procedure states "design reviews must be conducted at appropriate stages in development such as the end of each design phase". It also states that "In the event that a design review is not required, this shall be documented in the DHF". The design plans for both the SNAPP and SNAPP-X state there are to be a minimum of two design reviews performed. Only one review was performed for each of these designs and the reviews are not dated. There was also no documentation in the design history file as to why reviews were not conducted at the end of each design phase, as required by the procedure.

6) Failure to have a validation procedure and to fully document the design validation for the SNAPP device; and failure to conduct design validation for the SNAPP-X device. [21 CFR 820.30(g)]

Your response to observations three through six pertaining to design control appears to be adequate. Your response states that the design history files will be refurbished; that Tiara Medical will be transitioned to the VIASYS Respitory Care, Inc. Quality Management System; and all Tiara Medical employees will receive training on VIASYS' design control system. You

state this transition will occur by [redacted] Please keep us informed of the progress of this corrective action. A follow up inspection will be required to assure that corrections are adequate.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days from the date you receive this letter of any additional steps you have taken or plan to take to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include any additional documentation for the corrective actions you have taken. For the corrective actions listed in your response that appeared adequate, we will evaluate the adequacy of their implementation during the next FDA inspection. If corrective action cannot be completed within the timeframes specified in your letter, state the reason for the delay and the timeframe within which the corrections will be completed.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by the FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt action to correct the violations and to bring your products into compliance.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District

Cc: Tiara Medical Systems, Inc.
14414 Detroit Ave #205
Lakewood, OH 44107